

REMARKS

Status of the claims:

With the above amendments, claims 21 and 26 have been amended. Claims 1-14 and 16-28 are pending and ready for further action on the merits. No new matter has been added by way of the above amendments. Claim 21 has been amended to correct a spelling error and claim 26 has been amended to provide correct antecedent basis. Entry of the amendments and reconsideration is respectfully requested in light of the following remarks. Should the Examiner not allow the application in the next communication, Applicants respectfully request that the Examiner enter the amendments to place the application in better form for appeal.

Rejections under 35 USC §102

Claims 1-4 are rejected under 35 USC §102(b) as being anticipated by Kakuda '866 (US Patent No. 5,501,866).

This rejection is traversed for the following reasons.

The Examiner asserts that "Kakuda disclose a composition that is generic to the issue of sleep-promotion." (see page 6 of the Office Action). Applicants strongly disagree. Kakuda '866 simply discloses a caffeine stimulation inhibitor containing theanine. Kakuda '866 only discloses that one can drink tea or coffee without impairing sleep by taking the caffeine stimulation inhibitor. Kakuda '866 says nothing of "sleep promotion". Applicants

respectfully point out that there are many causes of sleep disorders. Ingesting caffeine is not one of them. Kakuda '866 says nothing of sleep disorders and says nothing about promoting sleep. Thus, Kakuda '866 cannot be deemed to be generic for sleep-promotion.

Further, on page 6 of the Office Action the Examiner asserts "Furthermore, the particular sleep disorder does not impart patentability since the affect desired by the applicant has been shown to be obtained by the prior art." Nowhere does Kakuda '866 disclose or suggest any sleeplessness problems that are not caused by caffeine. Applicants fail to see where any generic or specific disclosure of promoting sleep due to sleep disorders appears in Kakuda '866. Moreover, Kakuda '866 fails to disclose or suggest any patients that have a sleep disorder. Accordingly, Applicants submit that the effects of the present invention are neither disclosed nor suggested by Kakuda '866. For the above reasons, Applicants submit that the rejection has been obviated. Withdrawal of the rejection is warranted and respectfully requested.

Rejections under 35 USC §103

Claims 5-28 are rejected under 35 USC §103(a) as being unpatentable over Kakuda '866 in view of Ekanayake '1628 (US Statutory Invention Registration H1628).

Applicants traverse.

Present Invention

The present invention, as recited in claim 5, relates to a method of promoting sleep comprising administering to a patient suffering from a sleep disorder a composition comprising sugar, L-theanine, flavor and tartaric acid.

Disclosure of Kakuda '866

Kakuda '866 discloses a caffeine stimulation inhibitor that is said to inhibit stimulation by combining the use of theanine extracted from tea leaves and/or a substance having theanine for its major active ingredient which is produced by extracting tea leaves with a solvent such as water, hot water or ethanol, chemical synthesis, microbial fermentation or plant tissue culturing. These active ingredients are said to be able to inhibit the stimulatory action of caffeine without degrading the quality, such as the flavor and aroma, of caffeine-containing beverages and foods, allowing persons hypersensitive to caffeine to consume caffeine-containing beverages and foods without worry over its effects.

Disclosure of Ekanayake '1628

Ekanayake '1628 discloses a process for the production of tea extracts comprising the steps of (a) extracting tea materials with water, (b) mixing the extract containing solution with protein, (c) acidifying the protein containing extract, and (d) separating the

precipitates formed. The resultant tea extracts is said to have reduced bitter and astringent flavors and low levels of polymerized or oxidized flavanols. The extracts are said to be suitable for use as beverages or can be blended with fruit flavors, fruit juices and other flavors.

Removal of the Rejection over Kakuda '866 in view of Ekanayake '1628

Claim 5 of the instant invention recites "a method of promoting sleep comprising administering to a patient suffering from a sleep disorder a composition comprising sugar, L-theanine, flavor and tartaric acid".

Applicants assert that the Examiner has failed to make out a *prima facie* case of obviousness with regard to the 35 USC §103(a) rejection over Kakuda '866 in view of Ekanayake '1628. Three criteria must be met to make out a *prima facie* case of obviousness.

- 1) There must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings.
- 2) There must be a reasonable expectation of success.
- 3) The prior art reference (or references when combined) must teach or suggest all the claim limitations.

See MPEP §2142 and *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991). In particular, the Examiner has failed to meet the third element to make a *prima facie* obviousness rejection.

Neither of Kakuda '866 nor Ekanayake '1628 disclose or remotely suggest a method of promoting sleep comprising administering a theanine composition to a patient suffering from a sleep disorder. In particular, neither Kakuda '866 nor Ekanayake '1628 mention the words "disorder", "disease", or any other related words. Thus, the combination of Kakuda '866 and Ekanayake '1628 cannot render obvious the instant invention because Kakuda '866 and Ekanayake '1628 fail to disclose the elements of the instant invention.

Applicants respectfully point out that inhibiting the effects of caffeine (e.g., the sleeplessness that may result from its ingestion) as disclosed in Kakuda '866 has nothing to do with promoting sleep in an individual that suffers from a sleep disorder. In other words, sleeplessness from consuming caffeine is not a sleep disorder. Ekanayake '1628 says nothing about sleep, let alone, sleep disorders. For this reason alone the rejection is inapposite.

Applicants also respectfully submit that none of claims 8-9 and 21-24 can be rendered obvious by the combination of Kakuda '866 and Ekanayake '1628 because neither of these references remotely

mention changes in body rhythm, insomnia, vigilance in middle of sleep, vigilance in early morning and disturbance of restful sleep as appears in these claims. Thus, the rejection over these claims is also inapposite.

Applicants also respectfully point the Examiner to column 3, lines 20-46 in Kakuda '866 wherein mice were given theanine in amounts of either 174 mg/kg (group C) or 1740 mg/kg (group D). The group C mice appeared to demonstrate the exact same effects as the mice that were given no theanine but given caffeine (group B). The group C mice showed higher spontaneous movement than the control mice (group A - i.e., those mice that were given neither caffeine nor theanine). Please see lines 25-29 in column 3. This demonstrates that theanine in a concentration of 174 mg/kg is not effective in inhibiting the effect of caffeine. The mice that were given 1740 mg/kg (group D) appear to exhibit the same effects as the control mice (group A - those that were given neither caffeine nor theanine) but considerably less than the mice that were given either caffeine alone (group B) or the mice that were given caffeine and theanine at 174 mg/kg (group C). The conclusion one could draw is that theanine is effective if the dosage is increased 10 fold to 1740 mg/kg but is ineffective at a dose of 174 mg/kg.

Applicants respectfully point out that claim 28 claims a dosage of 0.2 to 200 mg/kg. The dosage of theanine that is ineffective in Kakuda '866 (174 mg/kg) falls within this range. The dosage of theanine that is effective (1740 mg/kg) falls way outside of this range. Thus, it appears that Kakuda '866 appears to teach away from using theanine at a concentration that is claimed in claim 28.

Accordingly, in light of the above remarks, Applicants believe that a *prima facie* case of obviousness has not been made. Withdrawal of the rejection is warranted and respectfully requested.

With the above remarks and amendments, it is believed that the claims, as they now stand, define patentable subject matter such that passage of the instant invention to allowance is warranted. A Notice to that effect is earnestly solicited.

Pursuant to the provisions of 37 C.F.R. 1.17 and 1.136(a), Applicants respectfully petition for one (1) month extension of time for filing a response in connection with the present application. The required fee of \$110.00 is attached hereto.

If any questions remain regarding the above matters, please contact Applicant's representative, T. Benjamin Schroeder (Reg. No. 50,990), in the Washington metropolitan area at the phone number listed below.

Appl. No. 09/980,620

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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